incomplete information or the failure to provide significant information identified by a DOE contractor normally will be categorized based on the guidance in section VI, ''Severity of Violations''.

DOE recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, DOE must be able to rely on oral communications from officials of DOE contractors concerning significant information. In determining whether to take enforcement action for an oral statement, consideration will be given to such factors as

(a) The degree of knowledge that the communicator should have had regarding the matter in view of his or her position, training, and experience;

(b) The opportunity and time available prior to the communication to assure the accuracy or completeness of the information;

(c) The degree of intent or negligence, if any, involved;

(d) The formality of the communication;

(e) The reasonableness of DOE reliance on the information;

(f) The importance of the information that was wrong or not provided; and

(g) The reasonableness of the explanation for not providing complete and accurate information.

Absent gross negligence or willfulness, an incomplete or inaccurate oral statement normally will not be subject to enforcement action unless it involves significant information provided by an official of a DOE contractor. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to DOE by an official of a DOE contractor or others on behalf of the DOE contractor, if a record was made of the oral information and provided to the DOE contractor thereby permitting an opportunity to correct the oral information, such as if a transcript of the communication or meeting summary containing the error was made available to the DOE contractor and was not subsequently corrected in a timely manner.

When a DOE contractor has corrected inaccurate or incomplete information, the decision to issue a citation for the initial inaccurate or incomplete information normally will be dependent on the circumstances, including the ease of detection of the error, the timeliness of the correction, whether DOE or the DOE contractor identified the problem with the communication, and whether DOE relied on the information prior to the correction. Generally, if the matter was promptly identified and corrected by the DOE contractor prior to reliance by DOE, or before DOE raised a question about the information, no enforcement action will be taken for the initial inaccurate or incomplete information. On the other hand, if the misinformation is identified after DOE relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action normally will be taken even if it is in fact corrected.

If the initial submission was accurate when made but later turns out to be erroneous because of newly discovered information or advance in technology, a citation normally would not be appropriate if, when the new information became available, the initial submission was corrected.

The failure to correct inaccurate or incomplete information that the DOE contractor does not identify as significant normally will not constitute a separate violation. However, the circumstances surrounding the failure to correct may be considered relevant to the determination of enforcement action for the initial inaccurate or incomplete statement. For example, an unintentionally inaccurate or incomplete submission may be treated as a more severe matter if a DOE contractor later determines that the initial submission was in error and does not correct it or if there were clear opportunities to identify the error.

XI. Secretarial Notification and Consultation

The Secretary will be provided written notification of all enforcement actions involving proposed civil penalties. The Secretary will be consulted prior to taking action in the following situations:

a. Proposals to impose civil penalties in an amount equal to or greater than $100,000;

b. Any proposed enforcement action that involves a Severity Level I violation;

c. Any action the Director believes warrants the Secretary's involvement; or

d. Any proposed enforcement action on which the Secretary asks to be consulted.

PART 830—NUCLEAR SAFETY MANAGEMENT

Sec.

Subpart A—General Provisions

Subpart B—Design [Reserved]

Subpart C—Operations [Reserved]

Subpart D—Material Management [Reserved]

AUTHORITY: 42 U.S.C. 2201; and 7191.

SOURCE: 59 FR 15851, Apr. 5, 1994, unless otherwise noted.

§ 830.1 Scope.

This part governs the conduct of the Department of Energy (DOE) management and operating contractors and other persons at DOE nuclear facilities.

§ 830.2 Exclusions.

This part does not apply to:

(a) Activities that are regulated through a license by the Nuclear Regulatory Commission (NRC) or a State under an Agreement with the NRC, including activities certified by the NRC under section 1701 of the Atomic Energy Act;

(b) Activities conducted under the authority of the Director, Naval Nuclear Propulsion Program, as described in Public Law 98–525; or

(c) Activities conducted under the Nuclear Explosives and Weapons Safety Program relating to the prevention of accidental or unauthorized nuclear detonations.

§ 830.3 Definitions.

(a) The following definitions apply to this part:

Administrative Controls mean provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility.

Contractor means any person under contract with the Department of Energy with responsibility to perform activities in connection with a nuclear facility.

Department or *DOE* means the Department of Energy.

Document means recorded information that describes, specifies, reports, certifies, requires, or provides data or results. A document is not considered a record until it meets the definition of record.

Fissionable materials means a nuclide capable of sustaining a neutron-induced fission chain reaction (e.g., uranium-233, uranium-235, plutonium-238, plutonium-239, plutonium-241, neptunium-237, americium-241, and curium-244).

Graded Approach means a process by which the level of analysis, documentation, and actions necessary to comply with a requirement in this part are commensurate with:

(1) The relative importance to safety, safeguards, and security;

(2) The magnitude of any hazard involved;

(3) The life cycle stage of a facility;

(4) The programmatic mission of a facility;

(5) The particular characteristics of a facility; and

(6) Any other relevant factor.

Hazard means a source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation).

Implementation Plan means a document prepared by a contractor that sets forth:

(1) When and how the actions appropriate to comply with the requirements of a section of this part, including the requirements of a plan or program required by the section, shall be taken, and

(2) What relief will be sought if a contractor cannot attain full compliance with a requirement in a reasonable manner.

Item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support systems.

Nonreactor nuclear facility means those activities or operations that involve radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public. Incidental use and generating of radioactive materials in a facility operation (e.g., check and calibration sources, use of radioactive sources in

research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines) would not ordinarily require the facility to be included in this definition. Transportation of radioactive materials, accelerators and reactors and their operations are not included. The application of any rule to a nonreactor nuclear facility shall be applied using a graded approach. Included are activities or operations that:

(1) Produce, process, or store radioactive liquid or solid waste, fissionable materials, or tritium;

(2) Conduct separations operations;

(3) Conduct irradiated materials inspection, fuel fabrication, decontamination, or recovery operations;

(4) Conduct fuel enrichment operations;

(5) Perform environmental remediation or waste management activities involving radioactive materials; or

(6) Design, manufacture, or assemble items for use with radioactive materials and/or fissionable materials in such form or quantity that a nuclear hazard potentially exists.

Nuclear facility means reactor and nonreactor nuclear facilities.

Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency, any State or political subdivision of, or any political entity within a State, any foreign government or nation or other entity and any legal successor, representative, agent or agency of the foregoing; provided that person does not include the Department or the United States NRC.

Process means a series of actions that achieves an end or result.

Quality means the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance means all those actions that provide confidence that quality is achieved.

Quality Assurance Program or QAP means the overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Reactor means, unless it is modified by words such as containment, vessel, or core, the entire nuclear reactor facility, including the housing, equipment, and associated areas devoted to the operation and maintenance of one or more reactor cores. Any apparatus that is designed or used to sustain nuclear chain reactions in a controlled manner, including critical and pulsed assemblies and research, test, and power reactors, is defined as a reactor. All assemblies designed to perform subcritical experiments that could potentially reach criticality are also to be considered reactors. Critical assemblies are special nuclear devices designed and used to sustain nuclear reactions. Critical assemblies may be subject to frequent core and lattice configuration change and may be used frequently as mockups of reactor configurations.

Record means a completed document or other media that provides objective evidence of an item, service, or process.

Service means the performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

(b) Terms defined in the Act and not defined in these rules are used consistent with the meanings given in the Act.

(c) As used in this part, words in the singular also include the plural and words in the masculine gender also include the feminine and vice versa, as the case may require.

§ 830.4 General rule.

(a) No person shall take or cause to be taken any action inconsistent with the requirements of this part or any program, plan, schedule, or other process established by this part.

(b) With respect to a particular DOE nuclear facility, the contractor responsible for the design, construction, operation, or decommissioning of that facility shall be responsible for implementation of, and compliance with, the requirements of this part.

(c) When a section of this part expressly requires a plan, program, or implementation plan, the provisions of

any such plan, program, or implementation plan, as approved by DOE, shall be the basis used to determine compliance with the relevant nuclear safety requirements in the section.

§ 830.5 Enforcement.

The requirements in this part are DOE Nuclear Safety Requirements and are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties in accordance with the provisions of part 820 of this title.

§ 830.6 Records.

A person shall maintain complete and accurate records as necessary to substantiate its compliance with the requirements of this part.

§ 830.7 Graded approach.

(a) Where indicated in a subpart, a graded approach shall be utilized to comply with the requirements.

(b) Whenever a graded approach is applied in meeting a DOE nuclear safety requirement, the bases for selecting an action pursuant to the graded approach shall be documented.

Subpart A—General Provisions

§ 830.100 Scope of subpart.

This subpart prescribes requirements that are generally applicable to more than one phase of the life cycle of a DOE nuclear facility.

§ 830.120 Quality assurance requirements.

(a) *General Rule.* (1) A contractor responsible for a DOE nuclear facility shall:

(i) Conduct its work in accordance with the criteria of paragraph (c) of this section;

(ii) Develop and submit for approval by DOE a Quality Assurance Program (QAP) for the work; and

(iii) Implement the QAP, as approved and modified by DOE.

(b) *Quality Assurance Program.* (1) A contractor shall develop a QAP by applying the quality assurance criteria specified in paragraph (c) of this section. A QAP shall include a discussion of how the criteria of paragraph (c) of this section will be satisfied. The criteria of paragraph (c) of this section shall be applied using a graded approach. The contractor shall use appropriate standards, wherever applicable, to develop and implement its QAP.

(2) Within 180 days after May 5, 1994, a contractor shall submit to DOE for approval a current QAP and an implementation plan.

(3) A contractor may, at any time, make changes to an approved QAP. Changes made over the previous year shall be submitted annually to DOE for review. A submittal shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this section. Changes made to correct spelling, punctuation, or other editorial items do not require explanation.

(4) Implementation plans and QAPs shall be regarded as approved by DOE 90 days after submittal, unless approved or rejected by DOE at an earlier date, and shall include any modification made or directed by DOE.

(c) *Quality assurance criteria.*—(1) *Management* (i) *Program.* A written QAP shall be developed, implemented, and maintained. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP shall describe management processes, including planning, scheduling, and resource considerations.

(ii) *Personnel Training and Qualification.* Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.

(iii) *Quality Improvement.* Processes to detect and prevent quality problems shall be established and implemented. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to

identify items, services, and processes needing improvement.

(iv) *Documents and Records.* Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.

(2) *Performance*—(i) *Work Processes.* Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.

(ii) *Design.* Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.

(iii) *Procurement.* Procured items and services shall meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.

(iv) *Inspection and Acceptance Testing.* Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

(3) *Assessment*—(i) *Management Assessment.* Managers shall assess their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

(ii) *Independent Assessment.* Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

Subpart B—Design [Reserved]

Subpart C—Operations [Reserved]

Subpart D—Material Management [Reserved]

PART 835—OCCUPATIONAL RADIATION PROTECTION

Subpart A—General Provisions

Sec.

Subpart B—Radiation Protection Programs

Subpart C—Standards for Internal and External Exposure

Subpart D—[Reserved]

Subpart E—Monitoring in the Workplace